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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,587	03/29/2004	Daniele Pressato	2039-0124PUS2	2626
2292	7590	09/29/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 09/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

Application No.

10/812,587

Applicant(s)

PRESSATO ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-15 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 16-19 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/22/06.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.



**DETAILED ACTION*****Status of the Claims***

Claims 11 and 16-18 have been amended. Claims 1-24 are pending. Claims 1-10 and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 12-15 are also withdrawn at this time as not corresponding to the elected species.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed July 19, 2006 is insufficient to overcome the rejection of claims based upon 35 USC § 103 as set forth in the last Office action. The declaration posits that the Malson product would be undesirable to use and would actually be poisonous. However, the rejection was not on the ground that it would be obvious to use the Malson product, but rather the Della Valle product. The Malson reference was used to demonstrate that it was known to use crosslinked HA for the prevention of surgical adhesion and that it was desirable to minimize “alien” crosslinking products. What *actual* alien substances are comprised in the Malson product is irrelevant.

The declaration further states that while Malson may have reduced impurities, the crosslinked HA of the invention has no foreign molecules. The examiner agrees, and this is exactly the point of the rejection. The product disclosed by Della Valle—apparently identical to the product used in the instant method—would appear to be superior for just this reason. Per the previous Office action: “The artisan would be further motivated to use this product because it is



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crosslinked without incorporating into the covalent structure chemicals that could produce undesirable immunological/inflammatory reactions.”

The declarant further states her opinion that it is incorrect to think that any crosslinked HA can be substituted for any other. This opinion is otherwise unsupported. The examiner maintains that based on the state of the art, it would be reasonable to expect that the Della Valle crosslinked HA would have similar utility in the prevention of surgical adhesions as other crosslinked HA products disclosed in the art.

***Claim Rejections - 35 USC § 103***

Claims 11, 16, 19 and 24 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691), as set forth in the previous Office action.

Applicant's arguments filed July 19, 2006 have been fully considered but they are not persuasive. In response to this rejection, Applicant reiterates what was stated in the declaration. This is addressed above. Applicant further states that “obvious to try” is not the proper standard. The examiner agrees, and this is not the standard applied. Based on what is known in the art, it would be reasonable to expect success in using the Della Valle product in the instant method, not merely obvious to try.



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Claims 11, 16, 19 and 24 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and further in view of Matsuda et al (US 5,462,976), as set forth in the previous Office action.

Claims 11, 16, 19 and 24 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and further in view of Leshchiner et al (US 5,399,351), as set forth in the previous Office action.

Applicant's arguments filed July 19, 2006 have been fully considered but they are not persuasive. Applicant adds nothing further not already addressed above.

Claims 11, 16-19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and further in view of Dorigatti et al (WO 94/17837).

Claim 17 has been amended to depend from claim <sup>11</sup><sub>A</sub>. Della Valle and Malson teach as set <sup>LCM</sup> forth in the previous Office action. The combination of references does not teach the use of a biomaterial comprising a non-biodegradable synthetic polymer.

Dorigatti teaches the use of a HA derivative in combination with various synthetic polymers. This material has utility as an anti-adhesive product for use in surgery. See abstract; page 7, lines 6-28; examples; and reference claim 36.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the product disclosed by Dorigatti by the use of the HA product disclosed by Della Valle. As discussed previously, HA products are known generally to have



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anti-adhesive properties. Therefore, one of ordinary skill would reasonably expect success in preparing a multilayer product taught by Dorigatti using the Della Valle crosslinked HA.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



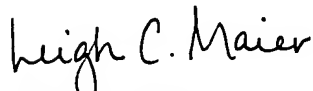
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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



Leigh C. Maier  
Primary Examiner  
September 27, 2006